

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/))	
FENFLURAMINE/DEXFENFLURAMINE)))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION))	
))	
THIS DOCUMENT RELATES TO:))	
))	
SHEILA BROWN, et al.))	CIVIL ACTION NO. 99-20593
))	
v.))	
))	
AMERICAN HOME PRODUCTS))	2:16 MD 1203
CORPORATION))	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8983

Bartle, J.

December 11, 2012

The Estate of Ginger S. Grogg, a.k.a. Marguerite G. Grogg ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Gregg S. Grogg, Gensa L. Baker, and Gaye Amaro, Ginger S. Grogg's ("Ms. Grogg" or "decedent") children, have also submitted derivative claims for benefits. The Trust, however, determined that the derivative claimants are not eligible to receive benefits.

3. Matrix Benefits are paid according to two benefit matrices
(continued...)

To seek Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the decedent's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In November, 2003, Gregg S. Grogg, the legal representative of the Estate of Ginger S. Grogg, submitted an amended Green Form to the Trust signed by the attesting

3. (...continued)

(Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1) - (2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators, or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

physician, Michael J. Liston, M.D.⁵ Based on an echocardiogram dated November 24, 1999, Dr. Liston attested in Part II of the Green Form that Ms. Grogg suffered from moderate mitral regurgitation⁶ and New York Heart Association Functional Class III symptoms. Dr. Liston further attested that Ms. Grogg had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™ and an ejection fraction of < 40% at any time six months or later after valvular repair or replacement surgery. Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$479,876.⁷

Dr. Liston also attested in the Green Form that the Ms. Grogg did not suffer from mitral annular calcification.

5. The Estate also submitted a Green Form in December, 2004 signed by Jeffrey S. Fierstein, M.D. The Trust contends this Green Form is not operative because it was submitted after the claim was complete and transferred to the Class Counsel Claims Office pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004). The Estate disagrees. We, however, need not resolve this dispute because the issue presented for our resolution is the same under both Green Forms.

6. Dr. Liston also attested that Ms. Grogg suffered from an abnormal left atrial dimension and a reduced ejection fraction in the range of 30% to 34%. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient qualifies for payment at Matrix Levels III or IV, had New York Heart Association Functional Class III or Class IV symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction < 40% six months after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)ii).

Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d. (2) (c)ii)d). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

In March, 2005, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists.⁸ In audit, Dr. Zwas concluded that there was no reasonable medical basis for Dr. Liston's finding that Ms. Grogg did not have mitral annular calcification. Specifically, Dr. Zwas explained that "[p]osterior, lateral, and medial [mitral annular calcification] is seen."

Based on the auditing cardiologist's finding that Ms. Grogg had mitral annular calcification, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁹ In contest, the Estate

8. Pursuant to PTO No. 3882, all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that the Estate had a Matrix A, Level V claim, pursuant to the PPP, the Trust audited the Estate's claim.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in (continued...)

argued that the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational, foolish, senseless, etc. from any medical perspective" and that a mere difference of opinion is insufficient to deny a claim for Matrix Benefits (emphasis in original).¹⁰ In addition, the Estate contended that there was a reasonable medical basis for the attesting physician's representation that Ms. Grogg did not suffer from mitral annular calcification because seven additional physicians have examined Ms. Grogg's mitral valve, either directly or by echocardiogram, and have not noted the presence of mitral annular calcification.¹¹

Although not required to do so, in July, 2005, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Zwas submitted a declaration in which she again concluded that there was no reasonable medical basis for

9. (...continued)

PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

10. The Estate also argues, in this and later submissions, that it should receive Matrix Benefits because the Trust did not timely complete Ms. Grogg's audit or otherwise comply with the timing requirements of the Audit Rules. The Estate, however, failed to demonstrate how it was prejudiced by this delay. As we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." PTO No. 6339 at 13 n.10 (May 25, 2006).

11. The Estate subsequently submitted a letter to the Trust arguing that the Trust subjected a prior Green Form to audit, rather than the Green Form of Dr. Fierstein.

the attesting physician's finding that Ms. Grogg did not have mitral annular calcification. In support of this conclusion, Dr. Zwas stated:

I again observed unquestionable evidence of mitral annular calcification on Ms. Grogg's November 24, 1999 echocardiogram. Mitral annular calcification is clearly observed in the parasternal view at frame 00357.01 (9:15:44 on the clock), and in the apical views at frame 00394.28 (09:00:45 on the clock).

Dr. Zwas also stated that whether the echocardiogram and cardiac catheterization reports noted mitral annular calcification was irrelevant to whether Ms. Grogg actually had mitral annular calcification. Finally, Dr. Zwas reviewed the January 18, 2000 angiogram and stated that it did not alter her conclusion.

Based on the second review, the Trust issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination, arguing that the Trust's record was incomplete as it did not contain reports of Ms. Grogg's December 1, 1994 and March 22, 1999 echocardiograms, which it attached. According to the Estate, the process was "tainted" and it was entitled to a new audit.

In September, 2005, the Trust forwarded the claim to Dr. Zwas for a third review. Dr. Zwas submitted an amended declaration in which she again concluded that Ms. Grogg had mitral annular calcification and that there was no reasonable medical basis for the attesting physician's representation to the

contrary. In addition, Dr. Zwas stated that she considered the two additional echocardiogram reports of December 1, 1994 and March 22, 1999 and concluded that they were irrelevant to whether Ms. Grogg's November 24, 1999 echocardiogram demonstrated mitral annular calcification. Dr. Zwas also explained that physicians interpreting echocardiograms do not always comment on every condition they observe, especially a common condition such as mitral annular calcification.

Thus, in October, 2005, the Trust issued an amended final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this amended final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on June 23, 2006, and the Estate submitted a sur-reply on August 10, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor¹² to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Grogg did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcile[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of its claim, the Estate reasserts the arguments it made in contest; namely, that none of the physicians involved in Ms. Grogg's care noted that she had mitral annular calcification. The Estate also objects to the fact that its claim was "audited" three times.

In response, the Trust argues that the medical records cited by the Estate do not establish a reasonable medical basis for the Green Form representation that Ms. Grogg did not have mitral annular calcification. According to the Trust, the issue is whether Ms. Grogg's November 22, 1999 echocardiogram, not other echocardiograms, demonstrates mitral annular calcification. In addition, the Trust contends that the "failure to note the presence of mitral annular calcification in an echocardiogram report does not negate its existence." The Trust also asserts that a surgeon would not be in a position to view mitral annular calcification and that the pathologist only was given a portion of the mitral valve and not the annulus.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Grogg's echocardiogram and medical records and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Grogg did not have mitral annular calcification. Specifically, Dr. Vigilante found that:

This study demonstrated obvious significant mitral annular calcification. There was rather severe thickening of the posterolateral annulus with increased reflectance of echoes consistent with calcification. This was a definite diagnosis on this study. This is not even close to a

borderline call. The calcification also involved part of the mitral leaflets and subvalvular apparatus including chords. This calcification was also seen medially along the mitral annulus. The mitral annular calcification was noted in the parasternal long-axis view, parasternal short-axis view, apical four chamber view, apical two chamber view, and subcostal view.... The time frames documented by Dr. Zwas on the tape were reviewed in detail and, indeed, demonstrated obvious mitral annular calcification.

In response to the Technical Advisor Report, the Estate argues that Dr. Vigilante "is obviously a pawn of the Trust placed in a position to ensure that Claimants are summarily denied benefits that they are rightfully entitled to" The Estate also asserts that the opinions of Dr. Zwas and Dr. Vigilante are entitled to less weight than the opinions provided by Ms. Grogg's physicians because Dr. Zwas and Dr. Vigilante are not "clinical cardiologists" and many of the opinions provided by Ms. Grogg's physicians were not related to or dictated by litigation.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As an initial matter, the Estate does not adequately refute or respond to the findings of Dr. Zwas or Dr. Vigilante. Specifically, Dr. Zwas determined that the November 24, 1999 echocardiogram demonstrated mitral annular calcification "in the parasternal view at frame 00357.01 (9:15:44 on the clock), and in the apical views at frame 00394.28

(09:00:45 on the clock).¹³ Dr. Vigilante reviewed these frames and confirmed that they "demonstrated obvious mitral annular calcification."¹⁴ Rather than challenge these specific findings, the Estate relies on various echocardiogram and cardiac catheterization reports, an operative report, and a pathology report, each of which is silent on the presence of mitral annular calcification. Dr. Zwas, however, specifically noted that a cardiologist interpreting an echocardiogram will not always reference every condition observed, particularly when the condition is a common one like mitral annular calcification. In addition, the Trust contended that the surgeon who completed the surgical report noted that visibility of the mitral valve during surgery "was very poor" and that only a portion of the mitral valve, not the mitral annulus, was provided to the pathologist. The Estate did not address these contentions or identify any particular error in the conclusions of the auditing cardiologist or the Technical Advisor. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any

13. We also reject the Estate's contention that the claim should be paid because it was subjected to audit three times by the same auditing cardiologist. The Trust submitted the claim for second and third reviews based on arguments and information submitted by the Estate subsequent to the audit that Dr. Zwas had purportedly had not considered. We perceive nothing improper with this practice, and the Estate has not demonstrated how it was prejudiced by the second and third reviews of Dr. Zwas.

14. The Estate's arguments that Dr. Vigilante is biased or unqualified are also without merit. We appointed Dr. Vigilante, after determining that he possessed the necessary skills and expertise, to assist us in reviewing Matrix claims in the show cause process. See PTO No. 3212 at 9 (Jan. 14, 2004).

specific errors by them is insufficient to meet a the Estate's burden of proof.

We also disagree with the Estate's definition of reasonable medical basis. Without any discussion, the Estate relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court simply addressed the circumstances under which the court would appoint an impartial expert witness to be presented to the jury and, therefore, the case is not apposite. See Gallagher, 31 F.R.D. at 38. The Estate also relies on the definition of "unreasonable" in Black's. One of the definitions, however, is "not guided by reason." The word "unreasonable" does not always mean "irrational" as the Estate would have us believe and it does not mean that here. We are not persuaded that either Gallagher or Black's supports the Estate's position.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Ms. Grogg did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A benefits.